Technical Support to Implement New Vaccine Technologies

International Vaccine Technology Workshop
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Technical support considerations for implementing new vaccine technologies for developing country vaccine manufacturers

- Baseline-manufacture at least one licensed vaccine for human use
- Don't start with the most difficult technology
- Capacity/skills sets needs differ from manufacturer to manufacturer
- Begin with thorough assessment of facilities, equipment, and personnel

Technical support considerations for implementing new vaccine technologies for developing country vaccine manufacturers

- Common areas for improvement include: basic R&D, process/formulation development, QA/QC, clinical research
- Form a customized partnership focused on the needs of the developing country vaccine manufacturer.

Examples from PATH's experience

- 116e attenuated monovalent human rotavirus vaccine-India
- Bovine/human reassorted rotavirus vaccine-India/China/Brazil
- Pneumococcal conjugate vaccine-India/China
- Japanese B encephalitis vaccine-China
- Influenza vaccines

116E attenuated monovalent human rotavirus vaccine

- Primarily an Indian project to manufacture safe, effective, and affordable vaccines for Indian infants and others in developing world
- Complex partnership-BBIL/Department of Biotechnology-India/PATH
- PATH provides funding for clinical development and technical experience on cGMP and QA/QC
- Phase 3 clinical trials about to begin (T-4Q10)

Bovine/human reassorted rotavirus vaccine

- Reference strains constructed at US NIH and licensed to multiple developing country vaccine manufacturers
- PATH has built enabling technologies to accelerate/facilitate vaccine development. These include qualified Vero cells, qualified clinical assays, clinical severity scoring schemes, monoclonal abs for potency testing, polyclonal sera for adventitious agent testing, reference reagents, stabilizing formulations.
- PATH formed partnerships with specific manufacturers to further accelerate development by providing funding and technical assistance

Pneumococcal conjugate vaccine

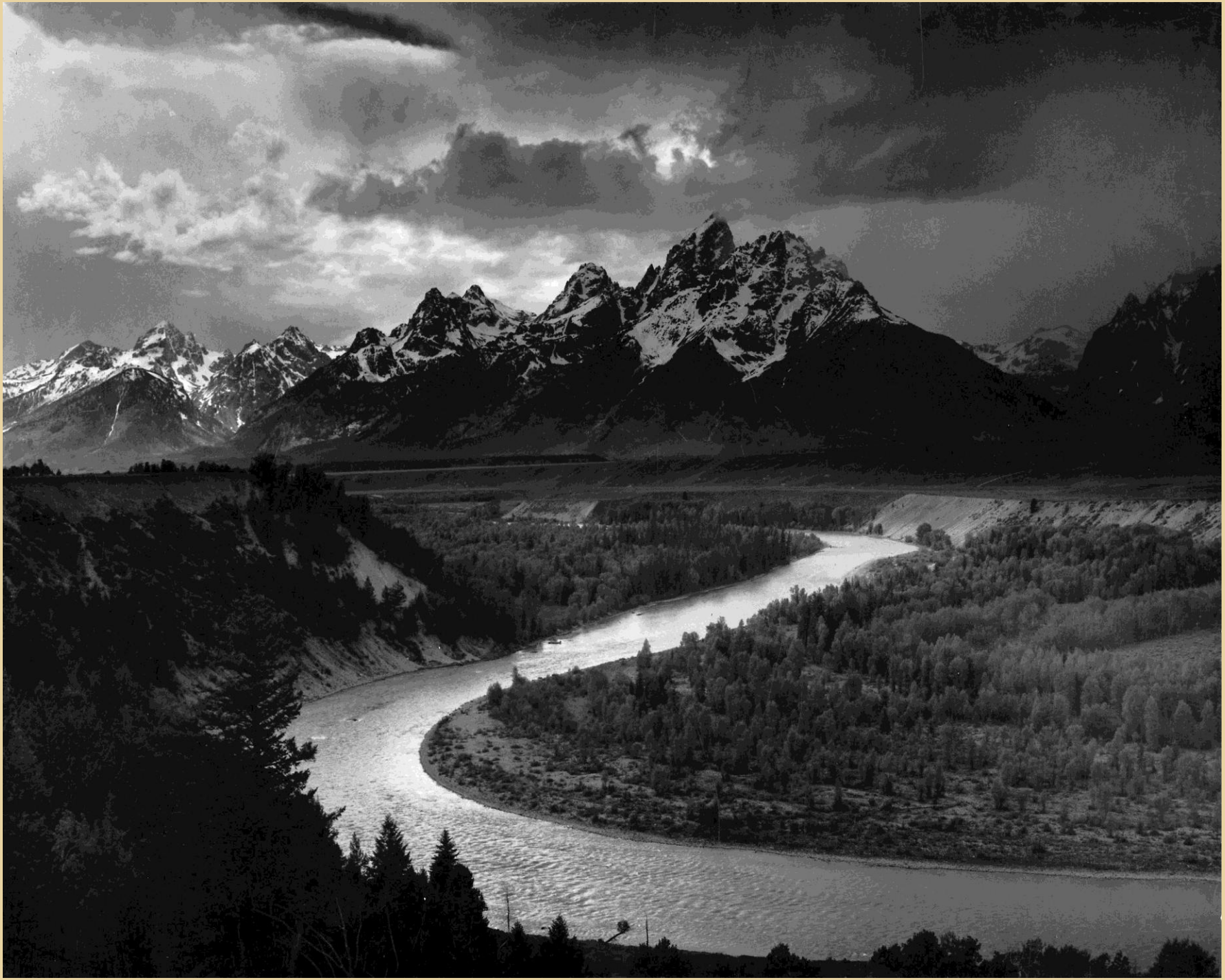
- Complex vaccine, especially conjugation chemistry, purification, yields, and analytical assays
- PATH formed partnerships with specific manufacturers to accelerate development by providing funding and technical assistance
- Primarily current technical assistance supported by cadre of ex-industry technical experts in bioprocessing, analytical assays, purification, and QA/QC
- Clinical development and regulatory affairs assistances needed as projects mature

Japanese B encephalitis vaccine

- Licensed vaccine (Chengdu), but not WHO-prequalified
- PATH formed partnership to facilitate licensure/availability of vaccine in Asian countries at risk and at an affordable price
- PATH provides extensive cGMP assistance to achieve WHO prequalification once China's NRA is declared functional by WHO

Influenza vaccines

- Inactivated flu vaccine
  - PATH formed partnership to privide technical assistance to company in Vietnam
  - Assistance primarily related to facilities and cGMP manufacture
  - Clinical trials assistance anticipated in future
- Live attenuated flu vaccine
  - PATH formed partnership to provide technical assistance to institute in Russia
  - Partnership dovetails with efforts by WHO
  - Assistance primarily related to developing new constructs for avian influenza
  - Clinical trials assistance anticipated in future



John W. Boslego, MD

jboslego@path.org

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